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EXAMINER

NOGUEROLA, ALEXANDER STEPHAN

ART UNIT PAPER NUMBER

1753

DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/974,597

Applicant(s)

KERMANI ET AL.

Examiner

ALEX NOGUEROLA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,2,6-10,17,23-28,31,32 and 36 is/are allowed.
- 6) ☒ Claim(s) 3-5,11-16,18-22,29,30,33 and 34 is/are rejected.
- 7) ☒ Claim(s) 35 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 August 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,12.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

Claim Objections

1. Claims 19 and 22 are objected to because of the following informalities:
 - a) Claim 19, line 4: -- the -- should be inserted between “determining” and “adequacy”;
and
 - b) Claim 22, line 2” “within” should be -- with --.
2. Claims 34 and 35 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer back to preceding claims only in the alternative. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.
3. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. Claims 3-5, 11-16, 18-22, 29, 30, 33, and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:
 - a) Claim 3, line 2: “measurement based” should be -- after --;

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- b) Claim 4, line 2: "said" should be -- an --;
- c) Claim 4, line 3: -- sample -- should be inserted before "volume";
- d) Claim 4: what is being compensated?
- e) Claim 11 recites the limitation "AC voltage" in line 1. There is insufficient antecedent basis for this limitation in the claim;
- f) Claim 14 recites the limitation "AC voltage" in line 1. There is insufficient antecedent basis for this limitation in the claim;
- g) Claim 18 should have a step of compensating for an inadequate volume of biological sample since, according to the preamble, this is what the method is for;
- h) Claim 18 recites the limitation "said inadequate sample volume" in lines 4-5. There is insufficient antecedent basis for this limitation in the claim;
- i) Claim 18: it is not clear what is being "compensated"?
- j) Claim 18: what is the "inadequate sample volume" inadequate for? From paragraph [0069] of the specification it seems that a sample solution volume is inadequate if it is not adequate "to make an accurate measurement of the selected characteristic, *e.g.*, concentration of the targeted analyte(s)." The sample volume must be at least adequate for a capacitance measurement; otherwise the claimed ratio could not be determined;
- k) Claim 19, line 3: -- within an electrochemical biosensor -- should be inserted between "sample" and ",";
- l) Claim 19, line 4 is indefinite because no purpose is specified for which adequacy is being determined?
- m) Claim 19: what is being compensated?

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- n) Claim 19, line 5: “a” should be -- said --;
- o) Claim 19, line 5: “an” should be -- said --;
- p) Claim 29, line 2: -- if it is -- should be inserted between “volume” and “determined”;
- q) Claim 33, line 2 is indefinite because no purpose is specified for which adequacy is being determined?
- r) Claim 33: what is to be compensated? and
- s) Claim 34 is directed to a kit, yet it includes method limitations;

5. Note that dependent claims will have the deficiencies of base and intervening claims.

Allowable Subject Matter

6. Claims 1, 2, 6-10, 17, 23-28, 31-32, and 36 are allowed.
7. Claims 18 and 19 would be allowable if rewritten or amended to overcome the rejections under 35 U.S.C. 112, second paragraph, set forth in this Office action.
8. Claims 3-5, 11-16, 20-22, 29, 30, 33, and 36 would be allowable if rewritten to overcome the rejections under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

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9. The following is a statement of reasons for the indication of allowable subject matter:

a) Claim 1 requires the steps of measuring the current generated by applying the alternating voltage and determining the capacitance of the biosensor from the measured current. Rosenberg et al. (WO 99/47907 A1) teaches away from measuring the current when determining the volume of sample in the electrochemical cell (page 10, lines 19-27; claim 76; and page 17, line 14 – page 18, line 11);

b) Claims 2-16 depend directly or indirectly from allowable claim 1;

c) Claim 18 requires compensating for inadequate biological sample volume. Newman et al. (WO 87/03095 A1), Garnham et al. (WO 97/39343 A1), and Rosenberg et al. (WO 99/47907 A1) determine at least one characteristic of a biological cell by making a capacitance measurement, but they do not disclose using a ratio of capacitance measurements to compensate for inadequate sample volume;

d) Claim 19 requires the step of compensating for an inadequate volume of the biological sample within the electrochemical biosensor based on a determination that the volume is inadequate. In Beatty et al. (WO 99/32881 A1) if the sample volume is not adequate for an accurate measurement then the measurement is not performed (page 8, line 23 – page 9, line 7 and page 15, lines 1-12);

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e) Claim 23 requires means for deriving the surface area of the cell covered by the biological cell sample from the cell capacitance and means for deriving the volume of the biological sample from the cell surface area. In the embodiment in Rosenberg (WO 99/47907 A1) in which the cell surface area is determined, it is determined from the measured current without determining the capacitance (page 12, line 21 – page 13, line 3). Rosenberg states, “the current directly reflects an amount of surface area of the electrodes being contacted by the test portion of the sample [emphasis added].” In the embodiment in Rosenberg in which volume is determined it is determined directly from capacitance and not indirectly from current (page 16, line 28 – page 17, line 4). Rosenberg states, “the liquid within the chamber is directly correlated to the measured capacitance” (page 17, lines 2-4). Rosenberg further teaches away from using capacitance in conjunction with current (page 17, line 29 – page 18, line 11);

f) Claims 24-26 depend directly or indirectly from allowable claim 23;

g) Claim 27 requires that the electronic circuit be configured to determine the capacitance of the cell from the measured current, before determining the surface area of the cell covered by the biological sample from the cell capacitance and determining the volume of the biological sample from the cell surface area covered by the biological sample. In the embodiment in Rosenberg (WO 99/47907 A1) in which the cell surface area is determined, it is determined from the measured current without determining the capacitance (page 12, line 21 – page 13, line 3). Rosenberg states, “the current directly

reflects an amount of surface area of the electrodes being contacted by the test portion of the sample [emphasis added].” In the embodiment in Rosenberg in which volume is determined directly from capacitance and not indirectly from current (page 16, line 28 – page 17, line 4). Rosenberg states, “the liquid within the chamber is directly correlated to the measured capacitance” (page 17, lines 2-4). Rosenberg further teaches away from using capacitance in conjunction with current (page 17, line 29 – page 18, line 11);

h) Claims 28-31 depend directly or indirectly from allowable claim 27;

i) Claim 32 requires the microprocessor to comprise means for determining the volume of the biological sample from the test strip surface area covered by the biological sample based on the measured current. Although Rosenberg teaches an embodiment in which is provided means for determining the volume of the biological sample, the sample volume is determined directly from capacitance and not indirectly from current (page 16, line 28 – page 17, line 4). Rosenberg states, “the liquid within the chamber is directly correlated to the measured capacitance” (page 17, lines 2-4).

j) Claim 33 depend directly or indirectly from allowable claim 32; and

k) Claim 36 requires means for deriving the surface area of the cell covered by the biological sample from the cell capacitance or from the ration of the cell capacitance to the cell resistance and means for deriving the capacitance and resistance of the cell from the measured current. In the embodiment in Rosenberg (WO 99/47907 A1) in which the cell surface area is determined, it is determined from the measured current without determining the capacitance (page 12, line 21 – page 13, line 3). Rosenberg states, “the current directly reflects an amount of surface area of the electrodes being contacted by the test portion of the sample [emphasis added].” In the embodiment in Rosenberg in which volume is determined directly from capacitance and not indirectly from current (page 16, line 28 – page 17, line 4). Rosenberg states, “the liquid within the chamber is directly correlated to the measured capacitance” (page 17, lines 2-4). Rosenberg further teaches away from using capacitance in conjunction with current (page 17, line 29 – page 18, line 11).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1300.

Alex Noguerola
Alex Noguerola

01/21/2004

Primary Examiner
TC 1753